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PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/790,488	
	Filing Date	March 1, 2004	
	First Named Inventor	Sherman, et al.	
	Art Unit	unassigned	
	Examiner Name	unassigned	
Total Number of Pages in This Submission	9	Attorney Docket Number	AM-101314USA

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please Identify below):
Remarks Customer No. 38199 Express Mail No. EU531570978US		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	HOWSON AND HOWSON Cathy A. Kodroff
Signature	
Date	June 2, 2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
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AM-101314USA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/790,488 Confirmation No.: unassigned
Applicant : Sherman, et al.
Filed : March 1, 2004
Art Unit : unassigned
Examiner : unassigned
Customer No. : 38199
Title : ANTINEOPLASTIC COMBINATIONS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicant submits to the Examiner the attached Forms PTO/SB/08AB document listing and this paper pursuant to 37 CFR §1.56 and §§1.97-1.98. Forms PTO/SB/08A/B are attached and copies of the documents are enclosed herewith. This Information Disclosure Statement is submitted more than three months from the filing date of this application but before the receipt of a first Office Action. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

Express Mail No. EU531570978US

REMARKS

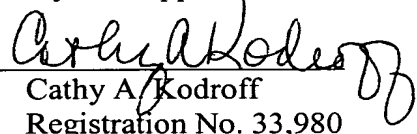
Listed below are previously filed, and co-pending, U.S. patent applications.
These applications and the present application are co-owned.

- (1) U.S. Patent Application No. 10/374,644, filed February 26, 2003
Publication No. US2003/0153593 A1, published August 14, 2003
(item US28)
- (2) U.S. Patent Application No. 10/116,902, filed April 5, 2002
Publication No. US2002/0183239 A1, published December 5,
2002 (item US20)
- (3) U.S. Patent Application No. 10/157,275, filed May 29, 2002
Publication No. US2002/0198137 A1, published December 26,
2002 (item US26)
- (4) U.S. Provisional Patent Application No. 60/552,122, filed March
11, 2004 (item US29)

The month of publication for documents L4, L5, L14, L17, L22, L23, L34, and L38 could not be determined. The years of publication for documents L4, L5, L14, L17, L22, L23, and L38 are sufficiently earlier than the effective US filing date and/or the foreign priority date of the present application so that the particular month of publication of the documents is not an issue (MPEP 609).

The Examiner is respectfully requested to consider the enclosed documents identified in this paper and in the attached Forms PTO/SB/08A/B during the course of examination of this application.

Respectfully submitted,
HOWSON AND HOWSON
Attorneys for Applicants

By 
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PTO/SB/08b (08-03)
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/790,488
				Filing Date	March 1, 2004
				First Named Inventor	Sherman
				Group Art Unit	unassigned
Examiner Name	unassigned				
Sheet	1	of	6	Attorney Docket Number	AM-101314USA

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	US1	3,929,992	12-30-1975	Surendra N. Sehgal, et al.	
	US2	3,993,749	11-23-1976	Surendra N. Sehgal, et al.	
	US3	4,401,653	08-30-1983	Chee P. Eng	
	US4	4,885,171	12-05-1989	Surendra N. Sehgal, et al.	
	US5	5,078,999	01-07-1992	Linda M. Warner, et al.	
	US6	5,080,899	01-14-1992	Robert J. Sturm, et al.	
	US7	5,100,899	03-31-1992	R. Calne, et al.	
	US8	5,206,018	04-27-1993	Surendra N. Sehgal, et al.	
	US9	5,286,730	02-15-1994	Craig E. Caufield, et al.	
	US10	5,286,731	02-15-1994	Craig E. Caufield, et al.	
	US11	5,288,711	02-22-1994	Robert D. Mitchell, et al.	
	US12	5,321,009	06-14-1994	William L. Baeder, et al.	
	US13	5,362,718	11-08-1994	Jerauld S. Skotnicki, et al.	
	US14	5,387,589	02-07-1995	Prasad S. Kulkarni	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ -Kind Code ⁵ (if known)				
	F1	EP - 0 525 960 - A1	02-03-1993	Glenn A. Miller, et al.		
	F2	WO02/066019 - A2	08-29-2002	Novartis AG		
	F3	WO99/52514 - A	10-21-1999	Eli Lilly and Company		X
	F4	WO02/13802 - A2	02-21-2002	American Home Product		

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS.
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Sheet	2	of	6	Attorney Docket Number	AM-101314USA

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	US15	5,496,832	03-05-1996	Jay J. Armstrong	
	US16	5,516,781	05-14-1996	Randall E. Morris	
	US17	5,561,138	10-01-1996	Jay J. Armstrong	
	US18	2002/0091137-A1	07-11-2002	Dukart, et al.	
	US19	5,066,493	11-19-1991	S.N. Sehgal, et al.	
	US20	2002/0183239-A1	12-05-2002	Gibbons, et al.	
	US21	2002/0183240-A1	12-05-2002	Gibbons, et al.	
	US22	2003/0050222-A1	03-13-2003	Rabindran, et al.	
	US23	6,002,008	12-14-1999	Wissner, et al.	
	US24	6,277,983	08-21-2001	Shaw, et al.	
	US25	6,617,333-B2	09-09-2003	Rabindran, et al.	
	US26	2002/0198137-A1	12-26-2002	Dukart, et al.	
	US27	5,728,710	03-17-1998	Luengo, Juan	
	US28	2003/0153593-A1	08-14-2003	Dukart et al.	
	US29	60/552,122	03-11-2004	Bayever et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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				Application Number	10/790,488
				Filing Date	March 1, 2004
				First Named Inventor	Sherman
				Group Art Unit	unassigned
				Examiner Name	unassigned
Sheet	3	of	6	Attorney Docket Number	AM-101314USA

NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	L1	S.N. SEHGAL, et al., Rapamycin (AY-22,989), A New Antifungal Antibiotic, II. Fermentation, Isolation and Characterization, J. Antibiot., October 1975, 727-732, 28	
	L2	C.V. VEZINA, et al., Rapamycin (AY-22,989), A New Antifungal Antibiotic, I. Taxonomy of the Producing Streptomycete and Isolation of the Active Principle, J. Antibiot., October 1975, 721-726, 28	
	L3	H.A. BAKER, et al., Rapamycin (AY-22,989), A New Antifungal Antibiotic, III. <i>In Vitro</i> and <i>In Vivo</i> Evaluation, J. Antibiot., June 1978, 539-545, 31(6)	
	L4	M.J. STARUCH, et al., FK506 and Rapamycin Inhibit Murine T Cell Activation Through Different Mechanisms, FASEB, 1989, 3411, 3	
	L5	F.J. DUMONT, et al., Rapamycin Blocks the Immunosuppressive Effect of FK506 But Not That of Cyclosporin A, FASEB, 1989, 5256, 3	
	L6	R.Y. CALNE, et al., Prolonged Survival of Pig Orthotopic Heart Grafts Treated with Cyclosporin A, The Lancet, June 3, 1978, 1183-1185	
	L7	R. MARTEL, et al., Inhibition of the immune response by rapamycin, a new antifungal antibiotic, Can. J. Physiol. Pharmacol., February 1977, 48-51, 55	
	L8	J. ALEXANDRE, et al., Rapamycin and CCI-779, Bull. Cancer, October 1999, pages 808-811, 86(10) (Only abstract of attached article has English translation)	
	L9	A. PERREN, et al., Immunohistochemical Evidence of Loss of PTEN Expression in Primary Ductal Adenocarcinomas of the Breast, Am. J. Pathology, October 1999, pages 1253-1260, 155, No. 4	
	L10	J.E. DANCEY, et al., Rapamycin-Sensitive Signal-Transduction Pathways: Protein Translation Control of Cell Proliferation, ASCO Educational Book, Spring 2000, pages 68-75	
	L11	M. HIDALGO, et al., The rapamycin-sensitive signal transduction pathway as a target for cancer therapy, Oncogene, December 27, 2000, 6680-6686, 19	
	L12	E.A. SAUSVILLE, et al., New Agents-Noncytotoxins, Antiangiogenesis, ASCO Educational Book, Fall 1998, pages 112-117	
	L13	T. SCHMELZLE, et al., TOR, a Central Controller of Cell Growth, Cell, October 13, 2000, pages 253-262, 103	
	L14	J. ALEXANDRE, et al., "CCI-779, a new rapamycin analog, has antitumor activity at doses inducing only mild cutaneous effects and mucositis; early results of an ongoing phase 1 study", Proceedings of the 10th NCI/EORTC/AACR Symposium, 1999 (poster presentation)	

Examiner Signature		Date Considered	
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				Application Number	10/790,488
				Filing Date	March 1, 2004
				First Named Inventor	Sherman
				Group Art Unit	unassigned
				Examiner Name	unassigned
Sheet	4	of	6	Attorney Docket Number	AM-101314USA

NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	L15	J.J. GIBBONS, et al., The effect of CCI-779, a novel macrolide anti-tumor agent, on the growth of human tumor cells <i>in vitro</i> and in nude mouse xenografts <i>in vivo</i> , Proceedings of the American Association for Cancer Research, March 1999, 301, #2000, v.40	
	L16	B. GEOERGER, et al., Rapamycin analog CCI-779 inhibits growth of human medulloblastoma xenografts, Proceedings of the American Association for Cancer Research, March 1999, 603, #3978, v.40	
	L17	B. GEOERGER, et al., Cytotoxic effects of rapamycin in human medulloblastoma cell lines and xenografts: as single agent or in combination chemotherapy, Proceedings of the American Association for Cancer Research, 1999, #296	
	L18	J. ALEXANDRE, et al., Phase I Study of CCI-779, Novel Rapamycin Analog: Preliminary Results, Proceedings of the American Association for Cancer Research, March 2000, 613, #3897, v.41	
	L19	M. HIDALGO, et al., Phase I and pharmacological study of CCI-779, a cell cycle inhibitor, Proceedings of the 11th NCI/EORTC/AACR Symposium, November 2000, 4548s, 6 (Supp.), #413	
	L20	M. HIDALGO, et al., A phase I and pharmacological study of CCI-779, a rapamycin ester cell cycle inhibitor, Annals of Oncology, October 2000, 133, 11(4)	
	L21	E. RAYMOND, et al., CCI-779, an ester analogue of rapamycin that interacts with PTEN/PI3 kinase pathways: A phase I study utilizing a weekly intravenous schedule, Proceedings of the 11th NCI/EORTC/AACR Symposium, November 2000, Abstract 414	
	L22	E. RAYMOND, et al., CCI-779, a Rapamycin Analog and Multifaceted Inhibitor of Signal Transduction: a Phase I Study, Proceedings of ASCO, 2000, 187a, 19, #726	
	L23	E. RAYMOND, et al., CCI-779, a Rapamycin Analog with Antitumor Activity: A Phase I Study Utilizing a Weekly Schedule, Proceedings of ASCO, 2000, 187a, 19, #728	
	L24	M. HIDALGO, Phase I and Pharmacological Studies with the Rapamycin Analog CCI-779 Administered as a 30 Minute Infusion, NCI-CTEP Drug Development Meeting, October 1999	
	L25	M. ABOU-GHARBIA, Medicinal Chemistry Approaches for Optimization of Early Leads in Drug Candidates: The Discovery of Calicheamicin, Rapamycin and EAA-090, International Conference on Pure and Applied Heterocyclic Chemistry, March 2000	
	L26	R. LANGRETH, et al., Drug Progress on Hard-to-Treat Cancers Is Cited, The Wall Street Journal, November 17, 1999, vol. 234	

Examiner Signature	Date Considered
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NONPATENT LITERATURE DOCUMENTS

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	L27	B. GEOERGER, et al., Antitumor Activity of the Rapamycin Analog CCI-779 in Human Primitive Neuroectodermal Tumor/Medulloblastoma Models as Single Agent and in Combination Chemotherapy, Cancer Research, Vol. 4, No. 61, February 15, 2001, pages 1527-1532, XP-001079526	
	L28	J. BONI, et al., Pharmacokinetics of escalating doses of CCI-779 in combination with 5-fluorouracil and leucovorin in patients with advanced solid tumors, European Journal of Cancer, Vol. 37, NR. Suppl. 6, page S68, XP001084492, October 2001	
	L29	GUPTA, R.A., et al., Combinations for Cancer Prevention, Nature Medicine, Vol. 6, No. 9, XP-002223840, September 2000	
	L30	TORRANCE, et al., Combinatorial Chemoprevention of Intestinal Neoplasia, Nature Medicine, Vol. 6, No. 8, XP-002223841, September 2000	
	L31	ALBERTS, et al., New Perspectives on an Old Friend: Optimizing Carboplatin for the Treatment of Solid Tumors, The Oncologist, Vol. 3, No. 1, pages 15-34, February 1998	
	L32	SCHWARTSMANN, Marine Organisms and Other Novel Natural Sources of New Cancer Drugs, Annals of Oncology, Vol. 11, No. 3, pages 23-243, XP-001070989, October 13, 2000	
	L33	PUNT, et al., A phase 1 Study of Escalating Doses of CCI-779 in Combination with 5-fluorouracil and Leucovorin in Patients with Advanced Solid Tumors, European Journal of Cancer, Vol. 37, No. Supplement 6, Page S17, October 2001	
	L34	CLACKSON, et al., Broad Anti-Tumor Activity of ap23573, an mTOR Inhibitor in Clinical Development, Proc. Am. Soc. Clin. Oncol. 22, page 220, abstract 882, 2003	
	L35	BASELGA, et al., CCI-779 study 204: Phase II, 3-arm study of CCI-779 in combination with letrozole in postmenopausal women with locally advanced or metastatic breast cancer: preliminary results, December 19, 2003 (abstract presented to ASCO for presentation in June 2004)	
	L36	Y. SHI, et al., Rapamycin Enhances Apoptosis and Increases Sensitivity to Cisplatin <i>in Vitro</i> , Cancer Research, Vol. 55, 9, May 1, 1995, pages 1982-1988, XP-002040888	
	L37	GREENBERGER, et al., A New Irreversible Inhibitor of Epidermal Growth Factor Receptor Tyrosine Kinase for the Treatment of Cancer, Clinical Cancer Research, Vol. 6, page 38, November 2000, XP-001120789	
	L38	CARTER, et al., Chemotherapy of Cancer, Second Edition, John Wiley & Sons, NY, NY, pages 362-365, 1981	

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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